



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b> <b>B29D 11/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/40395</b> <b>(43) International Publication Date:</b> 13 July 2000 (13.07.00)
<b>(21) International Application Number:</b> PCT/US99/24436 <b>(22) International Filing Date:</b> 18 October 1999 (18.10.99) <b>(30) Priority Data:</b> 60/114,366 30 December 1998 (30.12.98) US <b>(71) Applicant:</b> BAUSCH & LOMB INCORPORATED [US/US]; One Bausch & Lomb Place, Rochester, NY 14604-2701 (US). <b>(72) Inventors:</b> RUSCIO, Dominic, V.; 487 Joseph Circle, Webster, NY 14580 (US). BIDDLE, Graham, W.; 7156 County Line Road, Ontario, NY 14519 (US). <b>(74) Agents:</b> MAGEE, Mary, Anne et al.; Bausch & Lomb Incorporated, One Bausch & Lomb Place, Rochester, NY 14604-2701 (US).		<b>(81) Designated States:</b> AL, AU, BA, BB, BG, BR, CA, CN, CU, CZ, EE, GD, GE, HR, HU, ID, IL, IN, IS, JP, KP, KR, LC, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, SL, TR, TT, UA, UZ, VN, YU, ZA, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> METHOD AND MOLD FOR CASTING CONTACT LENSES		
<b>(57) Abstract</b>  A method of molding contact lenses in a mold made from a polyvinyl chloride material which lacks ultraviolet stabilizing agents produces an improved lens surface.		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## METHOD AND MOLD FOR CASTING CONTACT LENSES

### BACKGROUND OF THE INVENTION

The present invention pertains to methods for molding contact lenses, and especially improved mold materials for the contact lens molds in which the lenses are cast.

Various techniques for molding contact lenses are known in the art, including static cast molding. Static cast molding involves charging a quantity of polymerizable monomeric mixture to a mold assembly, and curing the monomeric mixture while retained in the mold assembly to form a lens, for example, by free radical polymerization of the monomeric mixture. Examples of free radical reaction techniques to cure the lens material include thermal radiation, infrared radiation, electron beam radiation, gamma radiation, ultraviolet (UV) radiation, visible light (including blue) and the like; combinations of such techniques may be used. The mold assembly defines a mold cavity for casting the lens, including an anterior mold for defining the anterior lens surface and a posterior mold for defining the posterior lens surface.

U.S. Patent No. 5,271,875, the entire disclosure of which is incorporated herein by reference, describes a static cast molding method that permits molding of a finished lens in a mold cavity defined by a posterior mold and an anterior mold. One embodiment described in this patent involves the use of polypropylene for the posterior mold and polyvinyl chloride (PVC) for the anterior mold. Curing of the lens-forming monomeric mixture retained in the mold cavity of the mold assembly can be achieved by free radical polymerization, especially, by directing UV radiation through the polypropylene posterior mold. One disclosed advantage of this combination of mold materials is that PVC of the anterior mold demonstrates a greater affinity for the cured lens material than

polypropylene of the posterior mold, thus ensuring that the cured lens is retained in the anterior mold when the mold assembly is disassembled, i.e., when the posterior and anterior molds are separated, the lens is selectively retained on the PVC anterior mold.

As recognized by US 5,271,875, polyvinyl chloride represents a suitable contact lens mold material. However, in the method described in US 5,271,875, it is important that the UV radiation is directed through the polypropylene posterior mold. This is because polypropylene permits transmission of UV radiation therethrough, whereas UV radiation is not adequately transmitted through a mold made from conventional PVC resins. In other words, attempts to cast a contact lens in a mold made of conventional PVC resins result in an inadequately cured lens due to inadequate transmission of UV radiation through the PVC mold. The inadequate curing can lead to various problems, such as lenses with inconsistent quality, surface tackiness, and/or surface defects.

It is also known to cure contact lenses by casting a monomeric mixture in a mold made of PVC, the mold including a surface for forming a desired anterior lens surface, wherein the monomeric mixture in the rotating mold is cured by exposure to UV radiation. In such a spincasting operation, the rotation of the mold can be controlled so that a desired posterior lens surface is formed. Alternately, an excess of monomeric mixture can be charged to the mold, and following curing of the lens-shaped article, a desired posterior lens surface can be lathe cut from the spuncast article. In both cases, the rotating mold is open from above, with UV radiation being directed to the monomeric mixture from above.

## SUMMARY OF THE INVENTION

This invention relates to cast molding of contact lenses in a mold made from a PVC material where radiation is directed through the PVC mold to cure the lens material. The PVC mold lacks UV absorbing agents conventionally added to PVC resin stabilizing packages.

More specifically, the invention relates to a method for molding contact lenses in a mold assembly comprising a posterior mold including a molding surface for defining a posterior contact lens surface and an anterior mold including a molding surface for defining an anterior contact lens surface. A monomeric mixture is charged to the mold cavity between the molding surfaces of the posterior and anterior molds, and this monomeric mixture is subjected to radiation while retained in the mold cavity to form a lens. One of the anterior and posterior molds is made of polyvinyl chloride free of UV absorbers, and radiation is directed through the mold made of polyvinyl chloride to the monomeric mixture in the mold cavity.

PVC resins conventionally include a UV stabilizer package that includes some type of UV absorbing agent. It was found that use of PVC resins free of such UV absorbers can be used to cure contact lenses, thus leading to various improvements in contact lens manufacture, such as lenses with reduced tackiness and improved optical quality, and improved lens handling by the consumer.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention is applicable for molding conventional contact lenses, such as those commonly referred to as soft hydrogel lenses prepared from a monomeric mixture including at least one hydrophilic lens-forming monomer. Conventional

hydrophilic monomers include: hydrophilic (meth)acrylate esters, such as hydroxyethyl methacrylate, hydroxyethyl acrylate and glycerol methacrylate; hydrophilic N-vinyl-containing monomers, such as N-vinyl pyrrolidone; hydrophilic (meth)acrylamides, such as N,N-dimethylacrylamide; and (meth)acrylic acids, including methacrylic acid and acrylic acid. The hydrophilic monomer may function as a crosslinking agent, or a separate crosslinking agent may be employed in the monomeric mixture, such as ethyleneglycol dimethacrylate or tetraethyleneglycol dimethacrylate. Additionally, since the monomeric mixture is cured by free radical photopolymerization, i.e., exposure to a source of radiation such as UV radiation to induce polymerization of the lens-forming monomers in the monomeric mixture, the monomeric mixture will generally include a minor amount of a free radical polymerization initiator known in the art. If desired, the monomeric mixture may further include a non-reactive solvent or diluent, or other components known in the art.

The monomeric mixture including a lens-forming monomer is charged to a mold cavity defined between lens molding surfaces of the anterior and posterior molds. At least one of these molds is made from PVC, and polymerization-inducing radiation, preferably UV radiation, is directed through this mold. This PVC mold is free of UV absorbing agents, including those conventionally included as part of the PVC resin package, so as to permit the lens material to be more completely cured by the photopolymerizing radiation. Alternately, both the anterior and posterior molds are made of the PVC resin free of UV absorbers, with UV radiation being directed through the posterior mold to the monomeric mixture retained in the mold cavity.

Commercial PVC resins generally include a stabilizing agent such as a UV absorber to prevent the molded product from yellowing, or otherwise deteriorate from

weathering, due to exposure to ambient UV radiation. Examples of stabilizers conventionally included in PVC resin packages are phenols, phenolic derivatives and benzotriazoles.

An advantage of the present invention over the aforementioned method described in US 5,271,875 is that both the anterior and posterior molds can be made from a PVC resin without restrictions as to the location of the radiation source. Additionally, thermoplastic resins such as polypropylene have a greater tendency than PVC to absorb oxygen. As disclosed in US Patent No. 5,681,510, dissolved or free oxygen in the contact lens mold can migrate to the interface between the molding surface of the contact lens mold and the surface of the lens, inhibiting free radical polymerization of the lens-forming monomer (thus affecting quality of the lens surface at this interface) and/or increasing tackiness of the lens surface (thus making the lens more difficult to handle by a consumer). However, this invention makes possible employing only PVC molds, whereas the problems attributed to oxygen transfer from the thermoplastic molds to the cast lenses are avoided.

The following examples serve to illustrate the invention.

#### EXAMPLE 1

Cast molded lenses were made generally following the procedure in US 5,271,875, except the posterior mold was made with PVC absent any UV stabilizer. This custom-made PVC resin was obtained from Georgia Gulf and injection molded into contact lens molds using conventional injection molding methods. A monomeric mixture composed mainly of 2-hydroxyethyl methacrylate was charged to the molding surface of the anterior mold and the posterior mold was placed thereon to form a molding cavity. UV light was directed through the posterior mold to cure the lens-forming

mixture in the mold cavity. Following curing, the posterior and anterior molded surfaces were disassembled; the lens remained with the anterior mold. The lens was then hydrated to facilitate removal from the anterior mold.

A test was developed to determine the tackiness or self-adherence of the posterior side of the contact lens to the molding surface of the posterior mold. The lens is folded in half so that the posterior lens surface lies upon itself. The folded lens is then placed between a pair of glass cover slips. A weight is placed on top of the cover slip, leaving a portion of the folded edges outside the cover slips for attachment. The weight is applied for 2 minutes. The lens is removed from the cover slips and cut into a strip leaving the 2 mm free edge section at the end of the strip. The free edge sections are taped with Teflon tape and clamped into the Instron Tensile Tester grips with one taped edge on the upper grip and the other taped edge on the lower grip. With the sample between the grips, the testing area of the Instron is immersed in a hydration tank and the sample is allowed to hydrate for 5 minutes. The force required to separate the two lens strips is then determined at the following conditions: Crosshead speed - 6.4 mm/min, Load cell - 254g, Gauge length - 5 mm and Sample width - 5 mm. The average peel strength for the sample is calculated and an average of 10 samples is reported.

For cast molded lenses made with anterior and posterior PVC absent UV stabilizer molds, 0.04 g/mm of pressure was required to separate the posterior lens surfaces.



## COMPARATIVE EXAMPLES

Following the general test procedure set forth above, additional lenses were made with the following results:

Example Number	Process	Posterior Mold Material	Pressure Required to Separate Posterior Lens Surfaces
C1	Spin Cast/Lathe	None	0.04g/mm
C2	Cast Mold	Polypropylene	0.25g/mm
C3	Cast Mold	Degassed Polypropylene	0.04g/mm

C1 represents an average of 10 lenses made from by the method previously described as spin casting. Using a PVC anterior mold, the mold surface is charged with excess monomer mixture and rotated while exposing the mixture to UV radiation to cure the mixture. Following curing, the posterior lens surface is then lathe cut. The combination of spin cast/lathed (C1) illustrates lenses that have a posterior surface which are completely cured without being exposed to a mold material with high oxygen content.

C2 represents the same average of 10 lenses cast molded, as in Example 1, with a posterior mold made of polypropylene and an anterior mold made of conventional PVC resin, with UV radiation being directed through the polypropylene posterior mold.

C3 also represents an average of 10 lenses. The posterior mold material was polypropylene and the anterior mold was PVC as in C2. However, the polypropylene molds were treated as described in US 5,681,510.

The results of the testing indicate that that lenses cast molded with a PVC posterior mold absent stabilizer (Example 1) require the same amount of force to separate

the lens surface as those lenses made from the combination of spin cast/lathed (C1) and those made with a degassed polypropylene posterior mold (C3).

The result of this data indicates that the posterior lens surface of Example 1 lenses did not stick together when folded over on itself, even under pressure. The use of PVC without UV stabilizer requires no special treatment of the material or molds as with the degassed polypropylene material of US 5,681,510.

The present invention is not limited to the embodiments specifically disclosed herein. Many other modifications and variations of the present invention are possible to one skilled in the field in light of the teachings herein. It is therefore understood that, within the scope of the claims, the present invention can be practiced other than as herein specifically described.

We Claim:

1. A method for molding contact lenses in an assembly, the mold assembly comprising a posterior mold including a molding surface for defining a posterior contact lens surface and an anterior mold including a molding surface for defining an anterior contact lens surface, comprising:

charging a monomeric mixture to a mold cavity between the molding surfaces of the posterior and anterior molds, and subjecting the monomeric mixture to UV radiation while retained in the mold cavity to form a lens,

wherein one of the anterior and posterior molds is made of polyvinyl chloride free of UV absorbers, and UV radiation is directed through the mold made of polyvinyl chloride to the monomeric mixture in the mold cavity.

2. The method of claim 1, wherein both the anterior and posterior molds are made of polyvinyl chloride free of UV absorbers, and UV radiation is directed through one of the molds to the monomeric mixture in the mold cavity.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/24436

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 B29D11/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B29D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 681 510 A (VALINT JR PAUL L ET AL) 28 October 1997 (1997-10-28) cited in the application ---	1
A	US 5 271 875 A (SILBERMANN STEVEN D ET AL) 21 December 1993 (1993-12-21) cited in the application ---	1
A	EP 0 876 900 A (JOHNSON & JOHNSON VISION PROD) 11 November 1998 (1998-11-11) ---	1
A	US 4 614 624 A (NEEFE CHARLES W) 30 September 1986 (1986-09-30) ---	1
A	EP 0 347 043 A (PILKINGTON VISIONCARE INC) 20 December 1989 (1989-12-20) ---	1
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

25 April 2000

Date of mailing of the international search report

08/05/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Roberts, P

# INTERNATIONAL SEARCH REPORT

In. ational Application No

PCT/US 99/24436

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 359 539 A (ALLERGAN INC) 21 March 1990 (1990-03-21) ---	1
A	EP 0 635 347 A (CIBA GEIGY AG) 25 January 1995 (1995-01-25) -----	1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/24436

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5681510	A	28-10-1997	AU 3955995 A	06-05-1996
			CA 2199007 A	25-04-1996
			CN 1160372 A	24-09-1997
			DE 69507500 D	04-03-1999
			DE 69507500 T	27-05-1999
			EP 0785854 A	30-07-1997
			ES 2129869 T	16-06-1999
			JP 10507418 T	21-07-1998
			WO 9611782 A	25-04-1996
US 5271875	A	21-12-1993	AT 137441 T	15-05-1996
			AU 666497 B	15-02-1996
			AU 2565992 A	05-04-1993
			BR 9206432 A	19-09-1995
			CA 2113257 A,C	18-03-1993
			CN 1071877 A,B	12-05-1993
			DE 69210407 D	05-06-1996
			DE 69210407 T	05-12-1996
			EP 0603284 A	29-06-1994
			ES 2089562 T	01-10-1996
			HK 1001679 A	03-07-1998
			JP 6510496 T	24-11-1994
			MX 9205182 A	01-11-1993
			SG 44659 A	19-12-1997
			WO 9304848 A	18-03-1993
			US 5466147 A	14-11-1995
EP 0876900	A	11-11-1998	US 5861114 A	19-01-1999
			CA 2233556 A	30-09-1998
			JP 11038368 A	12-02-1999
US 4614624	A	30-09-1986	US 4659524 A	21-04-1987
EP 0347043	A	20-12-1989	US 4921205 A	01-05-1990
			CA 1328962 A	03-05-1994
			JP 1875110 C	26-09-1994
			JP 2018012 A	22-01-1990
			JP 5088647 B	24-12-1993
			MX 166390 B	06-01-1993
EP 0359539	A	21-03-1990	US 5076683 A	31-12-1991
			DE 68924819 D	21-12-1995
			DE 68924819 T	02-05-1996
			US 5300262 A	05-04-1994
EP 0635347	A	25-01-1995	AU 686627 B	12-02-1998
			AU 6753594 A	02-02-1995
			CA 2128381 A	22-01-1995
			FI 943379 A	22-01-1995
			JP 7068573 A	14-03-1995
			NO 942722 A	23-01-1995
			NZ 264039 A	24-11-1997
			US 5574554 A	12-11-1996
			US 5882698 A	16-03-1999
			ZA 9405328 A	28-02-1995